

## REMARKS

The agent for the applicant thanks the Examiner for the telephone interview held on February 16, 2007. At the interview, the agent for the applicant explained the nature of the invention and the differences between the claimed invention and the cited references. In particular, the agent noted that none of the cited references discloses a method of selecting a disease risk prediction model where the candidate models use non-genetic data as input and the goodness of fitting is assessed by weighting the deviation of prediction from observation with weights that are determined based on genetic data. The Examiner acknowledged that the cited references do not disclose such features but requested that the claims be revised to further clarify the claimed method. The Examiner and the agent also discussed the requirement for statutory subject matter and whether a post-processing step is required to satisfy the requirement.

Claims 1 to 15 and 17 to 30 are pending.

Independent claims 1 and 21 have been amended for clarification, and to incorporate the subject matter of former claims 2 and 3. Support for this amendment can be found at least in Figs. 1 and 7, and at paragraphs [0039], [0088], [0089], and [0090] as filed. Claims 2 and 3 have been amended in view of the amendment to claim 1. Support for these amendments can be found at least at paragraph [0089]. Claims 4, 9, 19 and 23 have been amended to be consistent with current claim 1.

New claims 28 to 30 are presented for consideration by the Examiner. Support for claim 28 can be found at least in Figs. 1 and 7, at paragraphs [0039], [0060], [0088], [0089], [0090], and [0093], and claims 1 to 3, as filed. Support for claim 29 and 30 can be found at least at paragraph [0088] and in claim 1 as filed.

In particular, Fig. 1 shows that a computing device 100 outputs a risk predication model 116. Paragraph [0039] discloses "candidate model stored at computing device 100". Further, paragraph [0039] discloses that the parameters of the candidate model are optimized by fitting and "[t]he resulting model may be taken as the risk prediction model

116". Paragraph [0087] discloses that "an optimal candidate model 116 may be determined for a given combination of genetic data, by fitting non-genetic data 112 in all data sets 104 to the candidate model and optimizing the parameters (such as coefficients  $\beta_i$ ). The goodness of fit is assessed taking into account of the corresponding weights 114." Paragraph [0060] discloses that "[t]he corresponding weights 114 reflect the effects of genetic risk factors on the disease risk ". Paragraph [0088] discloses that "several candidate models may be stored at computing device 100 and used to find an optimal statistical model". Fig. 7 and the accompanying description also disclose that "the model that produces the minimum value of the weighted sum of deviates [...] may be selected as the risk prediction model 116" (paragraph [0089]). Paragraph [0090] discloses that "[t]he candidate statistical model that best fits the non-genetic data, [...] may then be used as a prediction model to predict the risk of disease for the subject of interest."

#### Statutory Subject Matter

Claims 1-15, 17-20 and 22-27 are rejected under 35 USC §101 as being directed to non-statutory subject matter.

Each of the independent claims 1, 22, and 27 has been amended and is now directed to a "computer-implemented method", and recites data transformation performed "at" or "by" a computing device or computer. As such, it is respectfully submitted that the amended claims 1, 22 and 27 are directed to statutory subject matter.

Claim 20 has been amended to clarify that the computing system comprises a tangible hardware, namely "at least one computing device".

Thus, it is believed that each of the current claims 1 to 15, 17 to 20, and 22 to 27 now complies with 35 USC §101.

New Matter

Former claims 1 to 15 and 17 to 27 have been rejected under 35 USC §112, first paragraph, as containing new matter.

The rejection to former claim 1 is moot in view of the current amendment to claim 1, where the expression “choosing said candidate model” has been deleted.

The rejection to former claim 21 is respectfully traversed. Specifically, the Examiner asserts that the limitation of “storing” a candidate model does not appear to be taught in the specification. As discussed above, at least paragraphs [0039] and [0088] disclose that candidate models may be “stored” at a computing device.

The rejection to former claim 27 as including new matter is also respectfully traversed. The previous amendment to former claim 27 is supported at least at paragraph [0083], which discloses that “each weight 114 ( $w_i$ ) may be adjusted to reflect the subject’s representation in the population” (emphasis added).

Thus, withdrawal of the new matter rejections is respectfully requested.

Indefiniteness

The Examiner rejected former claims 1 and 21 as it is unclear in what way the parameters are “so optimized”. This phrase has been deleted from current claims 1 and 21.

In response to the rejection to former claim 13 relating to the expression “indicative of a representativeness”, claim 13 has been amended to recite “an adjustment factor indicative of an extent to which the member associated with said each one of said plurality of said weights is representative of members of said population”. Support for this amendment can be found at least at paragraphs [0015] and [0083] of the description as filed.

Prior Art Rejections

The Examiner rejected former claims 1, 2, 3, 8-11, 13 and 19-21 under 35 USC §102(b) as being anticipated by Schoonjans, and claims 1, 2, 4 and 10 under 35 USC §102(b) as being anticipated by Fisher et al. The Applicant respectfully traverses these rejections.

Specifically, as clarified in current claim 1, the claimed method includes “optimizing [...] said parameters of said candidate model by fitting, wherein said fitting comprises: calculating for each of said sets, a deviate of a predicted risk from an indicator of disease status for that set, said predicted risk predicted using said candidate model and non-genetic data in that set; calculating a sum of weighted deviates for all of said sets, wherein each deviate is weighted in said sum by the weight associated with that set for which said each deviate has been calculated; and minimizing said sum of weighted deviates to obtain optimized parameters”. The “weights associated with sets of data having like genetic data are the same.”

In contrast, neither of the cited references discloses these features. Neither of these references discloses predicting risks using a candidate model and non-genetic data (or a first type of data), and optimizing the model parameters by minimizing the sum of weighted deviates where the deviates are weighted by corresponding weights that reflect genetic data (or a second type of data) associated with the respective data sets, as claimed in the current claim 1.

For at least these reasons, it is respectfully submitted that current claim 1 is not anticipated by either of the cited references.

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For similar reasons, amended claim 21, and claims 2 to 20 which are dependent directly or indirectly from current claim 1, are also distinguishable from the cited references. Thus, withdrawal of these rejections is respectfully requested.

Likewise, it is believed that new claims 28 to 30 are also allowable over the cited references.

No new matter has been added by this amendment.

In view of the foregoing, favourable consideration of the application is respectfully requested.

Respectfully submitted,

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